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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,986	05/03/2001	Andreas Bernkop-Schnurch	030560-056	7285

21839 7590 04/09/2003

BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

SHARAREH, SHAHNAH J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 04/09/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/830,986	BERNKOP-SCHNURCH, ANDREAS
Examiner	Art Unit	
Shahnam Sharreh	1617	

— The MAILING DATE of this communication appears in the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 27 August 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1 and 28-108 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1, 28-108 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.	6) <input type="checkbox"/> Other: _____.

DETAILED ACTION

Amendment filed on August 27, 2002 have been entered. Claims 1, 28-108 are pending.

Any rejection that is not addressed in this Office Action is considered obviated in view of arguments. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claims 1, 28-32, 100-106 are rejected under 35 U.S.C. 102(b) as being anticipated by Constancis et al US Patent 5,496,872.

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

Applicant argues that essentially argues that the polymers of Constancis are not mucoadhesive. Accordingly, the argument relies on the declaration filed on August 27, 2002 setting forth the characteristics of a mucoadhesive polymer and how the cited reference does not teach such features.

In response, Examiner states that under the principles of inherency, a prior art that does not expressly disclose claim limitations anticipates the claims, if it necessarily functions in accordance with, or includes, those limitations. *Atlas Powder Co. v. IRECO Inc.* 190 F.3d 1342, 1349 (Fed. Cir. 1999). Inherency is not necessarily coterminous with knowledge of those of ordinary skill in art, since artisans of ordinary skill may not recognize inherent characteristics or functioning of prior art, but discovery of previously unappreciated property of prior art composition or of scientific explanation for prior art's

functioning, does not render old compositions patentably new to discoverer. *Id.* Accordingly, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that references are nonetheless inherent in it. *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 630 (Fed. Cir. 1987).

In the instant case, the pending claims 1, 28-32 comprise two significant elements; a polymeric moiety having not more than 10 different monomers and at least one non-terminal thiol group. Constancis meets such limitation. Figure 1 and the abstract defines a polymeric moiety in the form of prepolymer or monomer having R1 and R2 as SH groups at the terminus of each unit (see abstract, col1, lines 39-66, col 2, lines 1-46). Accordingly, Constancis meets the elements of the instantly claimed polymers.

Subsequently, the mucoadhesive property of the polymer would be a functional property inherent to the elements of the polymer. Reasoned in *Atlas* inherent characteristics or functioning of prior art which was previously unappreciated property of prior art composition or scientific explanation for prior art's functioning, does not render old compositions patentably. Therefore, Constancis is anticipatory to the scope of rejected claims.

Further, the reliance on the Declaration filed on August 27, 2002, Paper No. 12 have been noted, but not impressive. "While the opinion testimony of a party having a direct interest in the pending litigation is less persuasive than opinion testimony by a disinterested party, it can not be disregarded for that reason alone and may be relied on when sufficiently convincing." *Ashland Oil, Inc v. Delta Resins & Refractories, Inc*, 227 USPQ 657 (CAFC 1985) at 665, citing *In re McKenna*, 97 USPQ 348 (CCPA 1953).

The proffered declaration fails to address the instant obviation's central issue; does the Constancis polymer provide mucoadhesive properties.

In the instant case, the declaration under 37 CFR 1.132 has been considered but is not found probative. Declarant concludes the claimed compounds would not adhere to the mucosa with the same strength as mucoadhesive polymers of the instant claims, because they do not fulfill the minimal criteria to be mucoadhesive. However, no evidence of such conclusion has been provided.

Further, the Declaration is not commensurate with the scope of the pending claims. The scope of the instant claims are neither directed to any specific level of adhesive strength, nor an improvement over the properties of the prior art of record. Furthermore, the pending claims are not directed to any specific minimal criteria for mucoadhesive properties as set forth in the declaration. The pending claims are solely limited to a polymer with an end functional sulfhydryl group. Constancis meets such limitations; therefore, it must possess at least some degree of mucoadhesion. Specifically, Constancis teaches his compositions to contain polysaccharides such as chitosan, dextran or mucopolysaccharides and further be used in dental surgery where their use is primarily for their cohesiveness or adhesive properties (col 4, lines 34-40, col 5, lines 5-14). Since mouth essentially is covered by mucus, the polymer of Constancis are viewed to possess mucoadhesive properties.

Claims 1, 28, 29, 31-38 stand rejected under 35 USC. 102 (b) as being anticipated by Moens (US Patent 5,670,468) for similar reasons as argued above.

Moen discloses thiol-containing polymers including polycysteine, therefore, it anticipates the limitations of the instant claims (col 8, lines 12-15; col 24, lines 45-60).

Claims 1, 28-108 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bernkop-Schnurch et al (Intl. J. Pharm. 157:17-25 (1997) and Int. J. Pharm. 146: 247-254 (1997) in view of Constancis US Patent 5,646,239.

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

Applicant's argument amounts to a distinction between bioadhesive and mucoadhesive compositions and that there is no suggestion to combine the references to come up with the instantly claimed compositions. In response to this argument Examiner states, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In the instant case, all elements of the pending claims are taught in the prior art. Bernkp-Schnurch teaches mucoadhesive polymers comprising chitosan-antipain conjugates. In fact, chitosan has long been proven to possess good adhesive properties for therapeutic purposes. Constancis teaches improved bioadhesive properties when such polymers are thiolated. Accordingly, forming a thiolated chitosan as suggested by the combined teachings of the references would have been obvious for preparing compositions with enhanced adhesive properties.

C nclusion

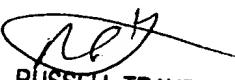
No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200